VaxCyne

Immunotherapeutic Vaccine Technology
Targets Cancer Biomarkers

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Cynvec was founded through a cancer research funding agreement with New York University and Dr. Daniel Meruelo in 2004

- Fund the basic research on Sindbis virus vector technology in the treatment of cancer
- Worldwide, exclusive license to NYU technology
- Strong and deep IP portfolio

Development Milestones

- Derived proprietary, patent protected sindbis vector platform - CYN 101
- Established GMP production process and analytics
- Completed pharmacology, biodistribution, and short-term toxicology
- Pre-IND meeting with U.S. FDA in June 2009
- Discovered and patented the immunotherapeutic vaccine mechanism of action of sindbis vectors using cancer biomarkers
- Renamed the immunotherapeutic vaccine platform – VaxCyne

Developing VaxCyne to Target Cancer Biomarkers NY-EOS-1 and CEA

- Ovarian, Lung, Colorectal, Breast, Gastric Cancers

VaxCyne is Engineered to Produce Tumor Biomarkers (TAAs) When Injected for Immunotherapeutic Vaccination

Differences Between Normal and Cancer Cells are Biomarkers:

- Tumor Associated Antigens
- Targets for Immunotherapy

*National Cancer Institute
Prioritization of Cancer Antigens: Biomarkers of Medical Importance for Cancer Therapy*

*Clin Cancer Res 2009;15(17) September 1, 2009*
VaxCyne is a Platform for Product Development

VaxCyne Vectors are Derived from CYN101 Sindbis Viral Vector*

VaxCyne Vector Cloning Site = Rapid Engineering

NY-ESO-1 and CEA are High Priority Cancer Biomarkers: NCI*

Overexpressed in Numerous Cancers:
- Ovarian - Breast - Thyroid
- Lung - Gastric - Pancreatic
- Melanoma - Colorectal

Differentiation Between Normal and Cancer Cells:
- Oncofetal Protein Not Expressed in Normal Adult Tissues

Poor Auto-Antibody Response:
- Activation of NK and T-Cells Needed for Effective Immune response

Combination with Chemotherapy – Immune Checkpoint Inhibitors:
- PD-1 Inhibitors**

**Matsuzaki et al. www.pnas.org/cgi/doi/10.1073/pnas.1003345107
How VaxCyne Works: Immune System Activation Against Tumor Biomarkers

*LacZ Biomarker Tumor Model*

- SV/LacZ
- LacZ
- gp70
- Anti-LacZ CD8+ T cell
- Anti-gp70 CD8+ T cell
- Antigen-presenting cell
- Natural killer cell
- LacZ(+) tumor cell
- LacZ(-) tumor cell (escape variant)
- Apoptotic tumor cell
- Lymph node

Surviving Mice are Resistant to Tumors and Have Immunity Against Tumor Biomarkers

Sindbis/LacZ-cured Mice Reject WT Tumor Cells and Have Memory CD8+ T Cells Against an Endogenous CT26 Tumor Associated Antigen (gp70)

Granot T, Yamanashi Y, Meruelo D. Molecular Therapy 2013
VaxCyne Technology Proof-of-Concept:
LacZ-specific CD8+ T cells Target and Destroy LacZ+ Tumor Cells

VaxCyne Immunotherapy with Tumor Biomarker Leads to 100% Survival

Granot T, Yamanashi Y, Meruelo D. Molecular Therapy 2013

FDA Reviewed Pre-Clinical & CMC

Rapid Path to IND for VaxCyne in Ovarian Cancer

CYN101 Biodistribution
- Tumors Not Normal Cells
- Lymph Nodes & Spleen

CYN101 Toxicology
- No Detectable Toxicity
- Acute
- 4-Week

CYN101 Pharmacology
- Tumor Reduction & Survival
- Induces NK and T-Cell Response
- Activates Epitope Spreading
- Synergistic with Chemotherapy

High-Yield GMP Vector Manufacturing & Purification
- Scalable In-Vitro Transfection Process
- Scalable Mammalian Cell Factory System
- Scalable Single-Column Purification

GLP Assays for Lot Release
- Titer/Quantification
- Potency/Biomarker Production
- Stability to 1 Year
Phase I Study of VaxCyne in Ovarian Cancer: 
Evaluation of Safety and Immune Response

TITLE: Phase I dose-escalation study of VaxCyne 
as intraperitoneal (IP) or intravenous (IV) 
immunotherapeutic consolidation in women with ovarian cancer

Principal Investigator: Franco Muggia 
Co-Principal Investigator: Mark Einstein

VaxCyne Activates the Immune System 
Against Cancer Biomarkers

Viral Vector Platform Enables Rapid Product Development 
Viral Antigens Enhance Immune Response Against Inserted Biomarkers

• Easily Engineered to Produce Tumor Associated Antigens:
  - Proteins
  - Peptides
  - RNA

• Activates Multi-cellular Immune Response
  - NK
  - CD-8 & CD-4 Lymphocytic T-Cells
  - Memory T-Cells

• VaxCyne Treats Tumors And Prevents Recurrence
  - VaxCyne with Tumor Biomarker Activates Immune System
  - Immune Cells Attack Tumor Cells Containing Viral and Biomarker Tumor Antigens 
  (Vector Infects Cancer Cells That Over-Express Laminin Receptor)

• Excellent Preclinical Results
  - Tumor Eradication - No Detectable Toxicity
  - Survival - Biodistribution Profile Demonstrates Mechanism
  - Immunity Against Cancer Recurrence
Cynvec is Raising Capital for the Clinical Development of VaxCyne for Cancer Immunotherapy

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<thead>
<tr>
<th>Cumulative Investment</th>
<th>Valuation Triggers</th>
<th>Months from Financing</th>
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<tbody>
<tr>
<td>$2.5 MM</td>
<td>VaxCyne Preclinical</td>
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<tr>
<td>$5 MM</td>
<td>VaxCyne Phase I Safety</td>
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<td>$10 MM</td>
<td>VaxCyne Phase I/II Preliminary Efficacy</td>
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A Single Ovarian Cancer Indication for VaxCyne Establishes Baseline Valuation for Cynvec

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<tr>
<th>Event</th>
<th>eNPV (M; risk adj.)</th>
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<tbody>
<tr>
<td>At start of Phase I</td>
<td>$34M</td>
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<tr>
<td>At start of Phase II</td>
<td>$84M</td>
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<tr>
<td>At start of Phase III</td>
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<tr>
<td>At Registration</td>
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<td>At Commercial Intro</td>
<td>$735M</td>
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eNPV Model Developed by The Frankel Group - 2009
VaxCyne Valuation Potential in Cancers Expressing NY-EOS-1 and CEA

- At start of Phase I: $263M
- At start of Phase II: $704M
- At start of Phase III: $2,602M
- At Registration: $4,957M
- At Commercial Introduction: $6,000M

eNPV Model Developed by The Frankel Group - 2009